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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,904	01/16/2004	Eric J. Beckman	02-012	1518

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/759,904		BECKMAN ET AL.	
	Examiner		Art Unit	
	James W. Rogers, Ph.D.		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 13,14,17,40-68 and 70-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/12/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of invention I in the reply filed on 08/15/2006 is acknowledged. The traversal is on the ground(s) that inventions I and IV should be combined. This is found persuasive because a search for groups I and IV will require search of essentially the same art and will not put an undue burden on the examiner. Thus group IV has been combined with group I.

The requirement for restriction between group I and groups II-III,V-IX is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,10-12,19-22,27,34-35 and 69 are rejected under 35

U.S.C. 102(b) as being anticipated by Liptova et al. (Macromol. Symp. 152,139-150 (2000), cited by applicant).

Liptova teaches hemocompatible (same as biocompatible) and biodegradable polyurethanes containing bioactive heparine fragments, which are

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prepared from diisocyanates, oligoetherglycols, chain extenders and heparin, which comprises a plurality of hydroxyl groups and has a therapeutic effect in the body. See pag 145-148 2nd paragraph. The biocompatible and biodegradable polyurethanes containing bioactive heparine fragments were used for the creation of artificial blood vessels.

Claims 1-4,7-8,12,19,22,27-30,33 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1, cited by applicant).

Woodhouse teaches biodegradable polyurethane materials synthesized from an amino acid based diisocyanate such as lysine, a polyol and an amino-acid chain extender. See col 2 lin 21-col 3 lin 30, col 6 lin 35-col 7 lin 5 and col 8 lin 20-39. Regarding the limitation of a bioactive agent with at least one reactive group -X, while Woodhouse teaches that the amino acids used are chain extenders, the amino acids within are degradable by enzymes thus meeting the limitation of a bioactive agent. Also the amino acids could have a plurality of reactive amine groups.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-39 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258, cited by applicants).

Zhang discloses biodegradable peptide-based urethane polymers synthesized by lysine diisocyanate (LDI) ethyl ester and glycerol (hydroxylated biomolecule) which were further reacted with water as the chain extender, forming foams for tissue engineering applications, the foams supported the growth of rabbit bone marrow stromal cells *in vitro*. See entire article. Zhang does not disclose in the experimental section a polyurethane embedded with a bioactive agent, however to do so would have been obvious due to the disclosure within that LDI-glycerol polymer may allow incorporation of proteins of interest (cell attachment factors and/or growth factors) to regionally promote a microenvironment optimal for cell organization and stimulation. See page 1248 left col, 1st paragraph. Regarding claim 23 the limitation of pore size is met by Zhang's disclosure that the pore size can be 10 μm to 2 mm in diameter. See page 1252, right col. 2nd paragraph. Zhang who disclosed that the free isocyanate content is 1.26% meets claims 24 and 36 limitation on the free isocyanate content. See page 1252 right col. 1st paragraph. Regarding claims 25-26 and 37-38 the NCO:OH equivalent limitations are met because Zhang discloses that 55 mmol of glycerol was added to 87 mmol of LDI, since LDI has two reactive sites (NCO) and glycerol has three (OH) the NCO:OH equivalent is 1.05.

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Claims 1-39 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258, cited by applicants) in view of Liptova et al. (Macromol. Symp. 152, 139-150 (2000), cited by applicant).

Zhang is disclosed above. Zhang while disclosing the peptide based urethane polymer may allow incorporation of proteins of interest such as cell attachment and/or growth factors does not give any working examples.

Liptova is disclosed above. Liptova is used to primarily show that it was already well known in the art at the time of the invention to incorporate bioactive proteins (heparin) into biodegradable polyurethane/polyol polymers.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Zhang discloses all of applicants claimed invention and even discloses the peptide based urethane polymer may allow incorporation of proteins of interest while Liptova is used to show that incorporating bioactive proteins (heparin) into biodegradable polyurethane/polyol polymers was already known in the art at the time of the invention. The motivation to combine the above documents would be to synthesize a biodegradable polyurethane containing a bioactive protein that may be applied as a prosthetic appliance in direct contact with living tissues. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

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Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

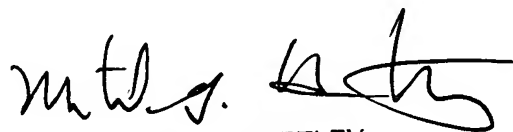
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (572) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (572) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private

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PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER